

Sub F1
59. A pharmaceutical composition comprising a compound of claim 27 and a pharmaceutically acceptable carrier.

B5 cont
60. A pharmaceutical composition comprising a compound of claim 56 and a pharmaceutically acceptable carrier.

F
61. A pharmaceutical composition comprising a compound of claim 58 and a pharmaceutically acceptable carrier.

Remarks

Reconsideration of this Application is respectfully requested.

The specification has been amended at page 1, lines 4-5, to reflect the present status of applications pertinent to the Cross Reference to Related Applications.

Upon entry of the foregoing amendment, claims 25-27, 35-53 and 55-61 are pending in the application, with 27, 46, 56 and 58 being the independent claims. Claims 1, 2, 28, 29 and 54 are sought to be canceled without prejudice to or disclaimer of the subject matter therein. New claims 58-61 are sought to be added. Support for new claim 58 can be found, *inter alia*, at page 23, line 21, through page 25, line 10, at page 25, lines 21-25, and in claims 1 and 25-27 of the application as filed. Support for new claims 59-61 can be found, *inter alia*, at page 29, line 7, through page 30, line 9, and in claim 34 of the application as filed. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully

request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Allowable Subject Matter

Applicants note with appreciation the Examiner's opinion that claims 27 and 54 contain allowable subject matter. Specifically, the Examiner stated that "[c]laims 27 and 54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims." (Office Action, page 5, paragraph number 7). Claim 27 has been amended to be independent. Claim 54 has been canceled and rewritten in independent form as new claim 58. Claims 27 and 58 incorporate any limitations of a base claim and any intervening claims. Applicants respectfully submit that claims 27 and 58 are fully in condition for allowance.

Election/Restriction

The Examiner has stated that "[c]laims 28, 29, 35-43, 47-53 and 56 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 6." (Office Action, page 3, paragraph number 2). Applicants have elected, with traverse, prosecution of compounds of Group II (compounds and compositions classified in class 540, subclass 3+, as described in Prosecution File Wrapper Paper No. 3, page 3, lines 6-7). Applicants note with appreciation the Examiner's statement that "upon allowance of the compound claims, method claims of the same

scope will be rejoined with the compounds allowed.” (Office Action, page 3, lines 6-7).

Claims 28 and 29 have been canceled. Applicants note that the allowable subject matter of claim 27 and claim 54 (now new claim 58) is directed to compounds wherein the substituent R₃ is selected from the group consisting of -C(O)-CH₂-Y-G, -C(O)-CH₂-O-D, -C(O)-CH₂-O-E, and -C(O)-CH₂-Z-G, where Y, G, D, E and Z are defined as in amended claim 46, above. For example, Y, G, D, E and Z groups that are present in the compounds of claim 27 include, *inter alia*, pyridyl, substituted phenyl, quinoliny and pyrrolidino. Claims 35-43, 47-53 and 56 are generic to the allowable subject matter of claims 27 and 54 (now new claim 58). Therefore, Applicants respectfully submit that claims 35-43, 47-53 and 56 read on the elected invention and are fully in condition for further consideration and allowance by the Examiner.

Rejections under the Judicially Created Doctrine of Obviousness-Type Double Patenting

The Examiner has rejected claims 1 and 2 under the judicially created doctrine of obviousness-type double patenting over claims 1-21 of U.S. Patent No. 5,925,630. (Office Action, page 4, paragraph number 4). Applicants respectfully traverse this rejection as it may apply to the amended claims.

Claims 1 and 2 have been canceled. Applicants respectfully submit that the Examiner's objection under the judicially created doctrine of obviousness-type double patenting has been overcome and should be withdrawn.

Rejections under 35 U.S.C. § 102

The Examiner has rejected claims 1, 2, 25, 26, 46, 55 and 57 under 35 U.S.C. 102(b) as being anticipated by Hosoda *et al.* Specifically, the Examiner is of the opinion that "Hosoda *et al.* teach 3 α -hydroxy-21-[(tetrahydro-2H-pyran-2-yl)oxy]-pregnan-20-one (see attached Abstract). The compound taught by the reference is encompassed by the instant claims." (Office Action, pages 4-5, paragraph number 6). Applicants respectfully traverse this rejection as it may apply to the amended claims.

The abstract supplied by the Examiner, CAPLUS accession number 1986:443183, reporting *Chemical Abstracts*, volume 105, abstract number 443183 (1986), appears to disclose 3 α -hydroxy-21-[(tetrahydro-2H-pyran-2-yl)oxy]-5 α -pregnan-20-one. 3 α -Hydroxy-21-[(tetrahydro-2H-pyran-2-yl)oxy]-5 α -pregnan-20-one contains a (tetrahydro-2H-pyran-2-yl)oxy group at the 21-position. A tetrahydro-2H-pyranyl group is heterocyclic, but it is not heteroaryl. In contrast, the compounds of the present invention all contain a substituent, at the 21-position, that is one of C-attached heteroaryl, optionally substituted aryl, a quaternary ammonium salt of a nitrogen containing heteroaryl group or a quaternary ammonium salt of an amino substituted aryl group. Thus, claims 1, 2, 25, 26, 46, 55 and 57 are not anticipated by the CAPLUS abstract of Hosoda *et al.* Applicants respectfully submit that the Examiner's objection under 35 U.S.C. § 102(b) has been overcome and should be withdrawn.

CAPLUS accession number 1986:443183 purports to be an abstract of Hosoda *et al.* *Chem. Pharm. Bull.*, 33:4281-4287 (1985). A copy of this reference is submitted herewith in a supplementary Information Disclosure Statement. Applicants have reviewed this reference and are unable to locate therein the reference compound, 3 α -hydroxy-21-[(tetrahydro-2H-pyran-2-

yl)oxy]-5 α -pregnan-20-one. The compounds disclosed in Hosoda *et al.* appear to be 11-deoxycortisol 21-acetate and derivatives of 5 α -dihydro-11-deoxycortisol 21-acetate, all of which appear to be substituted at the 17-position by a hydroxyl group. Applicants respectfully request that the Examiner point out where the reference compound can be found in Hosoda *et al.*

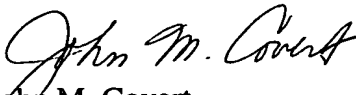
Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.


John M. Covert
Attorney for Applicants
Registration No. 38,759

Date: Mar. 23, 2000

1100 New York Avenue, N.W.
Suite 600
Washington, D.C. 20005-3934
(202) 371-2600